

EXHIBIT 38

1 IN THE UNITED STATES DISTRICT COURT

2 MIDDLE DISTRICT OF FLORIDA

3 TAMPA DIVISION

4
5 REBOTIX REPAIR, LLC

6 Plaintiff,

7 vs.

Case No. 8:20-CV-02274

8 INTUITIVE SURGICAL, INC.,

9 Defendant.

10 -----/

11
12
13 REMOTELY CONDUCTED

14 VIDEOTAPED DEPOSITION OF RONALD LEE BAIR, JR.

15 Livermore, California (Witness's location)

16 Monday, May 24, 2021

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19
20
21 Stenographically reported by:
LORRIE L. MARCHANT, RMR, CRR, CCRR, CRC
22 California CSR No. 10523
Washington CSR No. 3318
23 Oregon CSR No. 19-0458
Texas CSR No. 11318

24
25 Job No. 194222

1 next exhibit. This will be from Folder 3. I
2 believe this will be Exhibit 14.

3 THE STENOGRAPHER: I believe so.

4 (Marked for identification purposes,
5 Exhibit 14.)

6 MR. ERWIG: This will be 6'20'19 Bair to
7 Cooley.

8 BY MR. ERWIG:

9 Q. Screen share this with you, Mr. Bair. Do
10 you see this on the screen in front of you?

11 A. Yes, I do.

12 Q. I'll draw your attention to an e-mail a
13 little bit lower on this thread.

14 Do you recognize this e-mail from
15 June 20th, 2019?

16 A. Yes, it does ring a bell.

17 Q. How do you recognize it?

18 A. I authored it.

19 Q. What do you mean by that?

20 A. I wrote the e-mail from my e-mail address
21 and sent it to a sales representative -- I believe
22 Jack Groner is one of our key accounts directors --
23 and Matt Pate with whom we were working with at
24 USPI, or United Surgical Partners, I believe.

25 Q. And down below there's an e-mail from Jack

1 Groner to Matt Pate, yourself, and AJ Inacay.

2 Do you see that?

3 A. Yes.

4 Q. It mentions a third-party company that's
5 placing nonapproved computer chips back into an
6 instrument; is that right?

7 A. That is correct.

8 Q. Your response later up the thread is --
9 well, withdrawn.

10 Matt then sends a question to Jack Groner
11 that asks "What section of the contract prohibits
12 reprocessing?"

13 Do you see that?

14 A. Yes.

15 Q. Then you reply, "Hi, Jack/Matt. It's
16 traditionally in the second sentence of Section 3.4
17 of the sales license and service agreement."

18 Do you see that?

19 A. Yes.

20 Q. And you specifically cite something that
21 you refer to as standard language in a section in
22 its entirety. Do you see that?

23 A. Yes.

24 Q. That cited language is "Customer will not
25 nor will customer permit any third party to modify,

1 disassemble, reverse-engineer, alter, or misuse the
2 system or instruments and accessories."

3 Do you see that?

4 A. That is correct.

5 Q. Is it your understanding that that's
6 standard language in each sales contract that
7 Intuitive has with its hospital customers?

8 A. That is my understanding.

9 Q. And it's your understanding that the
10 standard -- withdrawn.

11 It's your understanding that the sales
12 license and service agreement is meant to stop the
13 hospitals from engaging third parties to repair
14 EndoWrists; right?

15 MS. LENT: Object to the form.

16 THE WITNESS: One implication of the
17 limited license would include, as stated here, third
18 parties engaging in activities that would modify,
19 disassemble, reverse-engineer, alter, or misuse the
20 system or instruments and accessories.

21 BY MR. ERWIG:

22 Q. And it's your understanding that, in the
23 manner in which those terms are written into the
24 contract, that hospitals are not permitted to
25 utilize third parties to perform repairs or services

1 on their EndoWrists; right?

2 A. Could you clarify what you mean, "service"?
3 As I mentioned, there are user serviceable
4 components, and reprocessing and sterilization --
5 disinfection, cleaning, reprocessing, sterilization,
6 et cetera, could all be considered permissible
7 services under the licensing as long as they do not
8 modify, disassemble, reverse-engineer, alter, or
9 misuse.

10 Q. Well, let's talk about disassemble. If a
11 third party inserts a chip into the EndoWrist to
12 reset the use counter, that would constitute a
13 violation of Section 3.4; is that right?

14 A. That is correct.

15 Q. And the purpose of the sales license and
16 service agreement is to stop hospitals from using
17 third parties to perform those types of
18 services; right?

19 MS. LENT: Object to the form.

20 THE WITNESS: We do not deem what you
21 stated to be a service, as I stipulated in my
22 previous response.

23 BY MR. ERWIG:

24 Q. Well, it's your understanding that the
25 sales license and service agreement is designed to

1 of the things you examined?

2 MS. LENT: Object to the form.

3 THE WITNESS: I believe one of the
4 objectives was potentially as it related to markets
5 or more cost-sensitive procedures. I don't know
6 that it was specifically related to individual
7 customers.

8 BY MR. ERWIG:

9 Q. Well, the refurbished instrument program,
10 it was your understanding that that program would
11 potentially expand the range of da Vinci surgeries
12 to other cost-sensitive procedures; right?

13 A. That may have been one mode or mechanism
14 through which we may have been able to achieve that
15 objective. That is correct.

16 Q. Intuitive never adopted a refurbished
17 instrument model despite the potential to impact new
18 markets; right?

19 MS. LENT: Objection. Asked and answered.

20 THE WITNESS: We have not launched a
21 refurbished program.

22 BY MR. ERWIG:

23 Q. Sir, that's because that refurbished
24 program, that would be a money loser for Intuitive;
25 right?

1 MS. LENT: Objection. Asked and answered.

2 THE WITNESS: As previously stated, there
3 are many reasons why we may decide to engage or not
4 engage in any specific business practices or the
5 development of products within our portfolio and our
6 road map.

7 MR. ERWIG: I'm going to screen share our
8 next exhibit. This will be Plaintiff's Exhibit 20.
9 This will be 8'15'19 Bair to Davis.

10 (Marked for identification purposes,
11 Exhibit 20.)

12 BY MR. ERWIG:

13 Q. Do you see this on the screen in front of
14 you, Mr. Bair?

15 A. Yes, I do.

16 Q. Do you recognize this?

17 A. Yes, I do.

18 Q. How do you recognize it?

19 A. It was -- the communication was forwarded
20 to me in advance of a visit that I was making to --
21 I believe it was the New Orleans area where this
22 customer may have been located.

23 Q. I want to scroll down to the first e-mail.
24 Who is Sherry Harvey?

25 A. She appears to have been the chief nursing

1 officer at Crescent City Surgical Centre.

2 Q. I want to point to some of the bullet
3 points in Ms. Harvey's e-mail.

4 In the first bullet Ms. Harvey writes,
5 "Please explain the notion that we have engaged in
6 the 'usage of unauthorized instrumentation.' What
7 gives Intuitive Surgical the right to determine how
8 Crescent City Surgical Centre uses instruments that
9 we own?"

10 Do you see that?

11 A. I do.

12 Q. Then in the second bullet point, Ms. Harvey
13 writes, "Please provide data that demonstrates that
14 patient safety is impacted by the safe, controlled
15 repair and reuse of robotic instruments."

16 Do you see that?

17 A. That is correct.

18 Q. Then Ms. Harvey goes on to say, "In lieu of
19 data that directly demonstrates this, please provide
20 any indication that patient safety is compromised.
21 Patient safety is our first concern, but we do not
22 act on vendor statements about safety; we act on
23 science."

24 Do you see that?

25 A. She was saying it a long time before all

1 the people were about COVID. Yes, I do.

2 Q. Were you able to provide Ms. Harvey with an
3 indication that patient safety was compromised by
4 the safe, controlled repair and reuse of robotic
5 instruments with the da Vinci surgical system?

6 A. I don't recall the final disposition of the
7 response to Ms. Harvey, but I am aware that it is
8 not incumbent on Intuitive to prove the safety or
9 efficacy of a third-party device or a device that
10 has been modified by a third party such that it is
11 rendered no longer an approved FDA device.

12 Q. Well, sir, that wasn't quite my question.
13 So let me reask it and focus on the question itself.

14 Were you able to provide Ms. Harvey with
15 any data that demonstrated that patient safety was
16 impacted by the safe, controlled repair and reuse of
17 robotic instruments?

18 MS. LENT: Objection to form.

19 THE WITNESS: I do not recall providing
20 data to Ms. Harvey related to products that have
21 been modified by other entities.

22 BY MR. ERWIG:

23 Q. Were you able to provide any indication to
24 Ms. Harvey that patient safety is comprised by the
25 safe, controlled repair and reuse of robotic

1 instruments?

2 MS. LENT: Object to the form.

3 THE WITNESS: We may have communicated to
4 Ms. Harvey that it was our understanding that these
5 modified devices were not approved by the
6 appropriate regulatory body whose principal aim and
7 objective is to protect patients as it relates to
8 both pharmaceuticals and medical devices. And so I
9 don't recall providing anything beyond that.

10 BY MR. ERWIG:

11 Q. I want to go to the next bullet point where
12 Ms. Harvey writes, "How does repair and reuse of
13 robotic instruments compromise 'product
14 performance'?"

15 Do you see that?

16 A. I do.

17 Q. Ms. Harvey writes, "We have audited the
18 quality system and testing protocols of our robotic
19 instrument repair partner as well as several
20 independent reports about materials degradation, and
21 we find no indication that the functionality of
22 robotic instruments is compromised when reusing the
23 instruments beyond the limited number of times
24 suggested by Intuitive Surgical."

25 Do you see that?

1 A. Yes, I do.

2 Q. Then Ms. Harvey asks, "Please provide test
3 results, studies, or data that document why the
4 instruments should be limited to 10 or 15 uses."

5 Do you see that?

6 A. I do.

7 Q. Did Intuitive perform any research as to
8 the functionality of robotic instruments that were
9 repaired by Ms. Harvey's robotics instrument repair
10 partner?

11 A. I'm not privy to. We may have engaged in
12 as it relates to testing of those products. I don't
13 believe that we were provided the opportunity to
14 partner with that organization that was engaging it,
15 and it was outside of my purview to explore those
16 sorts of questions.

17 Q. Mr. Bair, can you point the jury to any
18 scientific evidence that indicates that repair of
19 robotic instruments cannot safely be used for
20 surgery?

21 A. That is outside the scope of my
22 responsibilities as I do not engage in verification
23 and validation of our products prior to submission
24 to the FDA.

25 Q. Well, Ms. Harvey is certainly saying that

1 the robotic repair program is important in her
2 hospital's efforts to provide the best possible care
3 for her patients.

4 Do you see that?

5 A. I do see that.

6 Q. Then Ms. Harvey is asking some questions of
7 Intuitive to understand your claims about patient
8 safety.

9 Do you see that?

10 A. That is -- yes, I do see that.

11 Q. And were you able to provide any data to
12 Ms. Harvey in response to that request that the
13 safe, controlled repair and reuse of robotic
14 instruments was, in fact, compromising patient
15 safety?

16 MS. LENT: Objection. Asked and answered.

17 THE WITNESS: I believe the intent -- the
18 intent and spirit of our response was as it related
19 to compliance with the contract or the sales
20 licensing and service agreement that we'd engaged in
21 with Crescent City as well as our understanding and
22 awareness that Crescent City was using devices that
23 were not approved by the FDA or other regulatory
24 bodies.

25 ///

1 BY MR. ERWIG:

2 Q. Hospitals care about patient safety; right?

3 MS. LENT: Objection.

4 THE WITNESS: I don't know that I can speak
5 to all of the things that hospitals care about.

6 BY MR. ERWIG:

7 Q. Well, is it your understanding that
8 hospitals don't care about patient safety?

9 A. That is generally not my understanding.

10 Q. Is it generally your understanding that
11 hospitals, in fact, care very deeply for patient
12 safety?

13 MS. LENT: Objection.

14 THE WITNESS: I refer to my previous
15 response.

16 BY MR. ERWIG:

17 Q. Well, it's a question of your
18 understanding, sir, as it relates to hospitals. And
19 so I'll reask the question. Withdrawn.

20 Is it your understanding that hospitals
21 care about patient safety?

22 A. It is my understanding that that is an
23 element of the multitude of things that hospitals
24 care about.

25 Q. Ms. Harvey is, in fact, asking some

1 questions to determine whether Intuitive has any
2 data about the safety of repair of robotic
3 instruments; right?

4 MS. LENT: Objection. Asked and answered.

5 THE WITNESS: That is what she appears to
6 be asking about.

7 BY MR. ERWIG:

8 Q. Intuitive didn't provide any such data;
9 right?

10 MS. LENT: Objection. Asked and answered.

11 Can we move on?

12 THE WITNESS: I do not believe that we
13 provided data in response to this.

14 BY MR. ERWIG:

15 Q. Are you, in fact, aware, Mr. Bair, of any
16 data that was provided to any hospital that asked
17 Intuitive for data on patient safety related to the
18 repair and reuse of robotic instruments?

19 A. As I mentioned before, that's -- the data
20 related to verification and validation to
21 demonstrate the safe and effective use of these
22 products in the marketplace is outside of my
23 purview. And so I am not personally aware of any
24 instances where data has been provided, but there
25 certainly may have been as we are a fairly large

1 organization. And, again, I'm not an expert and/or
2 engaged in that space.

3 Q. Can you personally point to any data that
4 you've seen that indicates that repaired robotic
5 instruments are not able to be used safely by
6 hospitals?

7 MS. LENT: Objection. Asked and answered.

8 THE WITNESS: There was a reference in one
9 of the exhibits that we explored earlier in the day.
10 For example, the failure modes that were experienced
11 when instruments were attempted to -- where we
12 attempted to use them beyond their validated number
13 of lives. That's the extent to which that I have
14 personal exposure to anecdotal results of life
15 testing. But, again, that is outside of my purview
16 and area of responsibility.

17 BY MR. ERWIG:

18 Q. Now, sir --

19 We can stop screen sharing this exhibit.

20 Now, sir, you personally had communications
21 with hospitals that were using third-party repair
22 services for Intuitive's EndoWrists; is that right?

23 A. That is correct.

24 Q. In any of your communications with any of
25 those third-party -- withdrawn.